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*Application No. 10/075,053
Amendment dated April 19, 2007
Reply to Office Action mailed January 19, 2007***REMARKS**

This amendment is responsive to the Office Action mailed January 19, 2007 in connection with the above-identified patent application. In that Action, claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,951,539 to Nita, et al ("Nita"). Further, claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita in view of U.S. Patent Application Publication No. 2003/0109851 to Landuyt ("Landuyt"). Still further, claims 4, 5, 44, 45, 54, and 55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita as applied to claims 1, 41, and 52 and further in view of U.S. Patent No. 5,728,065 to Follmer, et al. ("Follmer"). Lastly, claims 4, 5, 44, 45, 54, and 55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita in view of Landuyt as applied to claims 1, 41, and 52 and further in view of Follmer.

Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 are Patentable Over Nita:

As noted above, claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 were rejected as being unpatentable over Nita. The Examiner took the position that in column 9 at lines 9-28, Nita teaches a continuous coil reinforcement member extending from the proximal end of the catheter and terminating at the distal end thereof. Further, the Examiner took the position that in Figure 5, the coil reinforcement member terminates at the second or distal end of the catheter and that Nita suggests that the distal nose tip section may not be present in the embodiment shown in Figure 5 or in the other figures where a distal nose tip section has been shown. For this, the Examiner cites to column 15 at lines 7-11. Further, the Examiner took the position that the catheter in Figure 10 is not specifically described as having a distal nose tip section and, therefore, according to the Examiner, this catheter is seen as having a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the second or distal end thereof.

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Applicant respectfully disagrees with the Examiner's interpretation of Nita. More particularly, the Examiner has read column 15, lines 7-11 out of context from the rest of the specification.

Beginning at line 5 in column 15, the specification of Nita describes a small "nose" or distal tip 311 of polymer which remains distal of the distal-most extension of the coil windings. Clearly, therefore, the presence of a "nose" or a distal tip formed of a polymer is present between the terminus of the coil windings and the distal end of the catheter.

Accordingly, therefore, Nita does not teach a continuous coil reinforcement member extending from the proximal end of the catheter and terminating at the distal end of the catheter.

The Examiner has read some of the lines of column 15 out of context with the rest of the specification. In particular, the Examiner cites to the seeming suggestion of removing the distal nose tip section from the catheter. However, the section cited to by the Examiner reads "[u]se of layers of coil in excess of the preferred dual layer distal-to-proximal layers is a feature independent of the presence or absence of other features, e.g., the distal nose tip section (311), shown in this figure or in others." It is respectfully submitted that the proper interpretation of this passage is that the use of layers of coil in excess of the preferred dual layer distal-to-proximal layers of the variation (embodiment) of the inventive catheter of Figure 5 is intended to be wholly independent of any of the other features of the embodiments described in the Nita patent and others of equivalent construction.

To fully support the above, applicant respectfully directs the Examiner's attention to the Nita specification beginning at column 15, line 65 whereat it is described that "[w]hen we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip (526). It is specifically noted that, however, the short distal tip (526) shown in Fig. 9 is not the same structural feature as is the comparatively lengthy most-distal section (502) in Fig. 5 which, in practice, may be 2.5 cm. or longer. Indeed, the bumper tip (526) may be used in conjunction with most-distal section (502)." (emphasis added)

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Thus, according to the above, the presence of a bumper tip is specifically included in each of the embodiments of the catheters described in Nita.

Thus, the Examiner's interpretation of Nita as teaching "that the distal nose tip section may not be present in the embodiment shown in Figure 5 or in the other figures" is inaccurate and against the explicit teachings of Nita.

In addition to the above, the Examiner cites Landuyt for a teaching of a desirability "to have the proximal portion of the catheter be more stiffer than the distal portion" and "the use of a harder material for the second coating to achieve the desired stiffness while maintaining a softer distal portion."

Without conceding the Examiner's position with regard to Landuyt, it is respectfully submitted that neither Landuyt nor Nita as argued above teach a continuous coil reinforcement member extending from one end of the catheter to the other end.

Next in the Office Action, the Examiner cites to the teachings of Follmer for showing a marker band disposed adjacent the distal end of the catheter.

Applicant respectfully submits that the Examiner needs to look no further than the teachings of Nita for a showing of a radio-opaque marker band such as shown at 108 in Figure 1, 204, 210 in Fig. 2, 236 in Fig. 3, 506, 508 in Fig. 8, and elsewhere in Nita. However, it is respectfully submitted that neither Follmer nor Landuyt, nor Nita as described above teach a catheter having a continuous coil reinforcement member extending from one tip of the catheter to the other.

Claims 1 and 3-11 are in Condition for Allowance:

Claims 1, 3, and 6-11 were rejected as being unpatentable over Nita.

Independent claim 1 recites a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the catheter, a first flexible outer coating covering the coil reinforcement member, and a second flexible outer coating covering a first portion of the first outer coating. Also, the claim includes the tubular member having a

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first end defining a proximal end of the catheter and a second end defining a distal end of the catheter.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to the Nita patent at column 6, lines 11-15 which suggest that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9 (column 5, l. 65). Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

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In addition to the above, the Landuyt and Follmer patent do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, it is respectfully submitted that independent claim 1 and claims 3-11 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 24 and 26-28 are in Condition for Allowance:

Independent claim 24 has been amended previously to clarify the claim in that the continuous coil reinforcement member element of the claimed reinforcement catheter stock is carried on the elongate flexible tubular member and extends from the lead end of the catheter stock to the trailing end of the catheter stock entirely. Applicants intend for this language to include the limitation that the continuous coil reinforcement member extends up to and terminates at the trailing end of the catheter stock as well as up to and at the lead end of the catheter stock. Simply, the continuous coil reinforcement member extends from end to end of the catheter stock.

As stated in the Nita patent beginning at column 15, line 65, it is described that "[w]hen we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip (526)."

For at least the above reasons, it is respectfully submitted that independent claim 24 and claims 26-28 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 41-51 are in Condition for Allowance:

Applicant has previously amended independent claim 41 to include the limitations of claim 42 wherein the coil reinforcement member element of the recited reinforced catheter is carried on the elongate flexible tubular member and extends from said first end of the tubular member and terminates at said second end of the tubular member.

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As stated in the Nita patent at column 15, line 65, it is described that "[w]hen we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip (526).

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to a portion of the Nita patent which suggests that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to a portion of the Nita patent which describes an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 41, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that

when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 41 of the present application.

In addition to the above, the Landuyt and Follmer patents do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, independent claim 41 and claims 42-51 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 52-60 are in Condition for Allowance:

Independent claim 52 recites a reinforced catheter comprising an elongate flexible tubular member having first and second ends and defining a lumen of the catheter, a continuous coil reinforcement member on the elongate flexible tubular member and terminating at said first and second ends of the tubular member, and first and second flexible outer coatings, the second flexible outer coating covering a first portion of the first flexible outer coating and the first flexible outer coating being softer than said second coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites a portion of to the Nita patent which suggests that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent

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does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to portions of the Nita patent which describe an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 52, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

In addition to the above, the Landuyt and Follmer patents do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, applicant respectfully submits that Independent claim 52 and claims 53-60 dependent therefrom are patentably distinct and unobvious over the references of record.

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Claims 61-64 are in Condition for Allowance:

Independent claim 61 has been previously amended to clarify the extent to which the coil reinforcement member extends on the elongate flexible tubular member comprising the reinforced catheter of the claim. More particularly, the coil reinforcement member element of the recited reinforced catheter includes the limitation of the reinforcement member being carried on the elongate flexible tubular member and extending in said distal tip of the catheter completely to said second end of the elongate flexible tubular member. In addition, the reinforced catheter claimed includes first and second outer coatings, the second outer coating covering a first portion of the first outer coating and the first coating being softer than the second coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 61 of the present application.

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In addition to the above, the Landuyt and Follmer patents do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, it is respectfully submitted that independent claim 61 and claims 62-64 dependent therefrom are patentably distinct and unobvious over the references of record.

Claim 65 is in Condition for Allowance:

Applicant has previously tendered an amendment to independent claim 65 to recite a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member on the elongate flexible tubular member and extending completely to and terminating at said second end of the tubular member, and first and second outer coatings, the second outer coating covering a first portion of the first outer coating and the first outer coating being softer than the second outer coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to a portion of the Nita patent which suggests that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to a portion of the Nita patent which describes an

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embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 65, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The applicants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

In addition to the above, the Landuyt and Follmer patents do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, applicant respectfully submits that independent claim 65 is patentably distinct and unobvious over the references of record.

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CONCLUSION

In view of the above amendments, comments, and arguments presented, it is respectfully submitted that all pending claims are patentably distinct and unobvious over the references of record.

Allowance of all pending claims and early notice to that effect is respectfully requested.

Respectfully submitted,

FAY SHARPE LLP

19 APR 07
Date

Michael E. Hudzinski
Michael E. Hudzinski, Reg. No. 34,185
1100 Superior Avenue, Seventh Floor
Cleveland, OH 44114-2579
216-861-5582

CERTIFICATE OF MAILING OR TRANSMISSION

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